

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Broyles *et al.*

Serial No.: 10/003,669

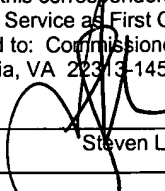
Filed: November 1, 2001

For: GENE REGULATION THERAPY
INVOLVING FERRITIN

Group Art Unit: 1632

Examiner: Janice Li Qian

Atty. Dkt. No.: OMRF:027US/SLH

CERTIFICATE OF MAILING 37 C.F.R. § 1.8	
I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date below:	
May 14, 2004 Date	 Steven L. Highlander

DECLARATION OF DR. XINLI LIN UNDER 37 C.F.R. §1.132

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450


I, the undersigned, do declare that:

1. I currently hold the position of Executive Vice President and Chief Scientific Officer at ProteomTech, Inc., Emeryville, CA. I have over 20 years of research experience in the fields of molecular, protein and cellular biology. A copy of my *curriculum vitae* is attached.

2. I am familiar with the work of Dr. Robert Broyles relating to ferritin-H as a repressor of the human β -globin gene in erythroid cells – when present in embryonic cells, it represses β -globin, but when absent in adult cells, β -globin is expressed. Thus, ferritin-H appears to be properly characterized as a hemoglobin switching factor.
3. Moreover, I am well aware of the implications this observation has in the treatment of β -globin-related diseases, such as sickle cell anemia. The relevant target cells for this condition (adult erythroid cells) have been shown to express ferritin receptors and to take up exogenously added ferritin protein, and other human cells (astrocytoma cells) which take up exogenous ferritin-H also transport it to the cell nucleus by an active transport mechanism. Thus, using ferritin-H or ferritin-H peptides as a therapeutic agent for treating sickle cell anemia is a logical extension of Dr. Broyles' work.
4. Regarding the feasibility of this approach, protein drugs have been used in clinical settings for several decades. For example, human insulin has been used to treat diabetics, and C-GSF has been used to treat infectious diseases and help to fight cancer. In addition, many other protein drugs have been approved by FDA in recent years, and our own company, which specializes in protein drug development, has many protein drug candidates in the pipeline. Thus, given what is known about the uptake and transport of ferritin-H, this protein is a promising candidate for treating indications such as sickle cell disease.

5. I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

5/12/04
Date


Xinli Lin, Ph.D.

CURRICULUM VITAE

Name: Xinli Lin

Address: ProteomTech, Inc.
5980 Horton St., Suite 405
Emeryville, CA 94608
Tel: 510-597-9134
FAX: 510-601-6751
ProteomTech, Inc.

Personal data: Marital status: married
Children: two

Education:

1987	Ph.D.	Virginia Polytechnic Institute and State University (Virginia Tech). Major: Biochemistry
1982	B.S.	Peking University, Beijing, China. Major: Chemistry

Honors:

1981-1984	Fellowship: CUSBMBEP (China-United States Biochemistry and Molecular Biology Examination Program)
1984-1985	Cunningham Year Fellowship: Virginia Polytechnic Institute and State University
1985	Graduate Student Research Grand Award by GSA: VA Tech
1988	Travel Grant Award for 14th International Congress of Biochemistry by IUB
1992	Merrick Award for Junior Scientist, OMRF
1999-2001	China Bridges International Fellowship Award
2000	Edward L. and Thelma Gaylord Prize for Scientific Achievement

Professional and Scientific Memberships:

American Society for Biochemistry and Molecular Biology.
 American Association for the Advancement of Science.
 American Society of Gene Therapy
 Ray Wu Society

Research and Professional Experience:

2001 to Present	Founder, Executive Vice President, Chief Scientific Officer (CSO), ProteomTech, Inc.
2002	Adjunct Member (Professor), OMRF
2000 to 2002	Associate Member, Head, Functional Proteomics Laboratory Director, Protein Expression Core, OMRF
2000 to 2002	Adjunct Associate Professor, Dept. of Pathology, University of Oklahoma Health Science Center (OUHSC)
1991 to 2000	Assistant Member, OMRF
1989 - 1991	Senior Research Scientist, OMRF
1986 - 1989	Associate Research Scientist, OMRF
1982 - 1986	Graduate Research with Dr. R. H. White, Virginia Tech
1981 - 1982	B.S. Thesis Research with Professor Sheng Jin, Dept. Chem., Peking University, Beijing, China

External Research Support:

Current Support:

- Source:** National Institute of Health #1 R43 CA103181-02
TITLE: Recombinant h-VEGI as an Anticancer Therapeutic
PI: Dan Medynski, Ph.D.
Co-PI: Xinli Lin, Ph.D.
Percent of Effort, Dr. Xinli Lin: 15%
Dates and Direct Cost of Entire Project: 07/01/04 - 06/30/06 \$750,000
- Source:** National Institutes of Health # 1 R43 CA105919-01
TITLE: Recombinant HbxAg Production for Anti-Cancer Therapeutic
PI: Xinli Lin, Ph.D.
Percent of Effort, Dr. Xinli Lin: 15%
Dates and Direct Cost of Entire Project: 05/14/04 - 11/13/04 \$100,000
- Source:** National Institutes of Health # R43 HL075883-01
TITLE: Bioengineering Prourokinase for Improved Fibrinolysis
PI: Dan Medynski, Ph.D.
Co-PI: Xinli Lin, Ph.D.
Percent of Effort, Dr. Xinli Lin: 10%

Dates and Direct Cost of Entire Project: 01/01/04 - 06/30/04 \$100,000

Prior Support:

Source: National Institute of Health #1 R43 CA103181-01

TITLE: Recombinant h-VEGI as an Anticancer Therapeutic

PI: Dan Medynski, Ph.D.

Co-PI: Xinli Lin, Ph.D.

Percent of Effort, Dr. Xinli Lin: 15%

Dates and Direct Cost of Entire Project: 08/01/03 - 01/31/04 \$100,000

Source: NIGMS 1 P50 GM62407-01

TITLE: Southeast Collaboratory for Structural Genomics

PI: Bi-Cheng Wang, Ph.D., University of Georgia

Percent of Effort, Dr. Xinli Lin: 15%

Dates and Direct Cost of Entire Project for Dr. Lin: 10/01/00 - 09/30/02 \$300,000

Source: National Institutes of Health

TITLE: Target-avoidance for HIV protease inhibitors

PI: Xinli Lin, Ph.D.

Percent of Effort: 15%

Dates and Direct Cost of Entire Project: 06/01/99 - 05/31/02 \$347,703

Source: Oklahoma Center for the Advancement of Science and Technology (OCAST)

TITLE: A Novel Chimeric Vector for *In Vivo* Gene Therapy

PI: Xinli Lin, Ph.D.

Percent of Effort: 10%

Dates and Direct Cost of Entire Project: 10/01/00 - 09/30/02 \$90,000

Source: Oklahoma Center for the Advancement of Science and Technology (OARS)

Title: Therapy for Cancer Using TK and VHS genes

PI: Xinli Lin, Ph.D.

Percent of Effort: 10%

Dates and Direct Costs of the Entire Project: 10/01/99 - 09/30/01 \$160,000

Source: NIH

PI: Xue-jun Zhang, PhD.

Title: Molecular Basis of Plasminogen-Streptokinase Interaction

Percent of Effort:: 10%

Dates and Direct Cost of Entire Project: 07/01/98 - 06-30-01 \$788,728

Source: NIH RO1 AI-CA42500-01

PI: Alice Mae Clark, Ph.D.

CO-PI: Xinli Lin, Ph.D.

Title: Candida Secreted Aspartic Proteases as Drug Targets

Percent of Effort: 15%

Dates and Direct Cost of Entire Project: 03-01-98 - 02-28-01 \$732,874

Source: Oklahoma Center for the Advancement of Science and Technology (OCAST),
H97-036

PI: Xinli Lin, Ph.D.

Title: *In Vivo* Gene Delivery in Human Gene Therapy

Percent of Effort: 20%

Dates and direct cost of entire project: 06-01-97 - 05-31-2000 \$105,000

Source: NIH RO1 53585-01

PI: Robert A. Floyd, Ph.D.

Title: Thiazine Dye Mediated Photokilling of HIV-1 Viruses

Percent of Effort: 10%

Dates and Direct Cost of Entire Project: 09-30-94 - 10-01-99 \$424,047

National Institutes of Health I R29AI34273 AARD

TITLE: *Protease Inhibitor Drugs for Candida Infections*

PI: Xinli Lin, Ph.D.

Percent of Effort: 50%

Dates and Direct Cost of Entire Project: 04/01/93 - 03/31/98 \$349,882

Oklahoma Center for the Advancement of Science and Technology (OCAST)

TITLE: *Industrial Application of Thermopsin* AR 2-010

PI: Jordan J.N. Tang, Ph.D.

CO-PI: Xinli Lin, Ph.D.

Percent of Effort: 15%

Dates and Direct Cost of Entire Project: 04/01/92 - 03/31/95 \$169,995.

Oklahoma Center for the Advancement of Science and Technology (OCAST)

TITLE: *Physiological Functions of Pregnancy-specific Antigen B* HN2-004

PI: Xinli Lin, Ph.D.

Percent of Effort: 30%

Dates and Direct Cost of Entire Project: 06/01/92 - 05/31/95 \$ 90,000

American Heart Association (Oklahoma Affiliate)--OK90G25

TITLE: *Decoding the Sorting Signals of the Regulated Secretory Pathway*

PI: Xinli Lin, Ph.D.

Percent of Effort: 75%

Dates and Direct Cost of Entire Project: 07/01/90 - 06/30/93 \$135,000

Invited Lectures:

Lin, X. Protein engineering on the N- and C-terminal lobes of pepsinogen and pepsin. Sept. 20, 1993. In: *The 5th International Conference on Aspartic Proteinases*", Gifu, Japan, Sept. 19-24, 1993. Organizing Committee Chairman: Dr. Kenji Takahashi, Tokyo University.

Lin, X. A series of four lectures for a European Common Market sponsored Advanced Course on "Structure and Function of Aspartic Proteases", which included student training in research techniques of molecular biology and protein engineering. May 23 to June 6, 1994, University of Coimbra, Portugal.

Lin, X. Invited to Conference on *Candida* protease and opportunistic infection, University of Mississippi, University, MS, February, 1997.

Lin, X. Seminar -- "A new *in vivo* gene delivery system for human gene therapy". Sol Sherry Thrombosis Research Center, Temple University School of Medicine, Philadelphia, PA, September 2, 1997.

Lin, X. Seminar series in Beijing, China. Topic: "A new *in vivo* gene delivery system for human gene therapy".

Sept. 10, 1997, Beijing Medical University.

Sept. 16, 1997, Beijing Red Cross Chao Yang University Hospital.

Sept. 19, 1997, Beijing People's University Hospital.

Lin, X. The 6th Symposium on Life Sciences and Biotechnology. Beijing, China. "Construction of new retroviral producer cells from adenoviral and retroviral vectors", August 7-10, 1998.

Lin, X. August 14, 1998, Shenyang Central Hospital, Chinese Medical University, Shenyang, China, "Human gene therapy: the past, the present, and the future".

Lin, X. August 20, 1998, Shenyang Central Hospital, Chinese Medical University, Shenyang, China, "Gene expression and functional studies of streptokinase and plasminogen"

Lin, X. "Studies on human memapsins". Sept. 11, 1999. In: *The 8th International Conference on Aspartic Proteinases*", Funchal, Madeira, Portugal, Sept. 7-12, 1999. Organizing Committee Chairman: Dr. Carlos Faro, University of Coimbra, Portugal.

Lin, X. November 12, 1999. "Identification of memapsin 2 as the beta-secretase that processes the amyloid precursor protein: implications in the treatment of Alzheimer's Disease". College of Life Science, Peking University, Peking, China.

Lin, X. July 23, 2000. "Structural Genomics and Functional Proteomics". The 2nd RWS Conference. Falmouth, MA.

Lin, X. Feb. 13, 2003. "Protein Refolding: from 'Art' to Science". ABRF (The

Association of Biomolecular Resource Facilities) 2003 Meeting, Denver, CO.

Lin, X. Oct. 5, 2003. “Automated High-Throughput Refolding Using a PTR Machine”. CBA 8th Annual Conference, Rockville, MD.

Patents:

1. Co-Inventor of Thermopsin - Patent No. 5,215,907, Issued June 1, 1993.
Title: Thermostable Acid Protease from *Sulfolobus acidocaldarius*.
2. Co-Inventor of Vectors for Human *in vivo* Gene Therapy – U.S. Patent No. 6,303,380, Issued Oct. 16, 2001.
Title: Construction of Retroviral Producer Cells from Adenoviral and Retroviral Vectors.
3. Co-Inventor of Napsin, A new human aspartic protease. – U.S. Patent No. 6,225,103. Issued May 1, 2001.
Title: “Cloning and Characterization of Napsin, an Aspartic Protease”
4. Co-Inventor of recombinant memapsin 2. – U.S. patent No. 6,545,127
Title: “Catalytically Active Recombinant Memapsin and Methods of Use Thereof”.
5. Inventor of ProteomTech’s core technology. – U.S. patent No. 6,583,268
Title: “Universal procedure for refolding recombinant proteins”.
6. Co-Inventor of streptokinase/plasmin structure
Title: Thrombolytic Agents Derived from Streptokinase. Patent Pending.
7. Co-Inventor of plasminogen-based plasminogen activator
Title: Human Plasminogen Activator. Patent Pending
8. Inventor of pro-urokinase refolding.
Title: Methods for production of recombinant urokinase
9. Inventor of VEGI-192a refolding, patent in preparation

Publications:

1. **Lin, X.**, and White, R.H. (1986) “Occurrence of coenzyme F420 and its γ -mono-glutamyl derivative in nonmethanogenic archaeobacteria”. *J. Bacteriol.* **168**:444-448.

2. **Lin, X.**, and White, R.H. (1987) "Structure of sulfohalopterins from *Halobacterium marismortui*". *Biochemistry*. **26**:6211-6217.
3. **Lin, X.** (1987) "Isolation and characterization of new pterins from nonmethanogenic archaeobacteria". Ph.D. Thesis, Virginia Polytechnic Institute and State University.
4. **Lin, X.**, and White, R.H. (1988) "Structure of sulfapterin (erythroneopterin-3'-D-2-deoxy-2-aminoglucopyranoside) isolated from the thermophilic archaeobacteria *Sulfolobus sulfataricus*". *J. Bacteriol.* **170**:1396-1398.
5. **Lin, X.**, and White, R.H. (1988) "Distribution of charged pterins in nonmethanogenic archaeobacteria". *Arch. Microbiol.* **150**:541-546.
6. **Lin, X.**, Wong, R.N.S., and Tang, J. (1989) "Synthesis, purification, and active site mutagenesis of recombinant porcine pepsinogen". *J. Biol. Chem.* **264**:4482-4489.
7. **Lin, X.**, and Tang, J. (1990) "Purification, characterization, and gene cloning of thermopsin, a thermostable acid protease from *Sulfolobus acidocaldarius*". *J. Biol. Chem.* **265**:1490-1495.
8. Fusek, M., **Lin, X.**, and Tang, J. (1990) "Enzymic properties of thermopsin". *J. Biol. Chem.* **265**:1496-1501.
9. **Lin, X.**, Fusek, M., Chen, Z., Koelsch, G., Han, H.-P., Hartsuck, J.A., and Tang, J. (1991) "Studies on pepsin mutagenesis and recombinant rhizopuspepsinogen". In: "*Aspartic Proteases*" (ed., Ben M. Dunn) Plenum Press, New York, NY, pp. 1-8.
10. **Lin, X.**, Fusek, M., and Tang, J. (1991) "Thermopsin, a thermostable protease from *Sulfolobus acidocaldarius*". In: "*Aspartic Proteases*" (ed., Ben M. Dunn) Plenum Press, New York, NY, pp. 255-257.
11. Lowther, W.T., Chen, Z., **Lin, X.L.**, Tang, J., and Dunn, B.M. (1991) "Substrate specificity study of recombinant *Rhizopus chinensis* aspartic proteinase". *Adv. Exp. Med. Biol.* **306**:275-279.
12. Chen, Z., Koelsch, G., Han, H.-P., Wang, X.-J., **Lin, X.**, Hartsuck, J.A., and Tang, J. (1991) "Recombinant rhizopuspepsinogen". *J. Biol. Chem.* **266**:11718-11725.
13. Lin, Y.-Z., Fusek, M., **Lin, X.L.**, Hartsuck, J.A., Kezdy, F.J., and Tang, J. (1992) "pH Dependence of kinetic parameters of pepsin, rhizopuspepsin, and their active-site hydrogen bond mutants". *J. Biol. Chem.* **267**:18413-18418.
14. **Lin, X.L.**, Lin, Y.-Z., Koelsch, G., Gustchina, A., Wlodawer, A., and Tang, J. (1992) "Enzymic activities of two-chain pepsinogen, two-chain pepsin, and the amino-terminal lobe of pepsinogen". *J. Biol. Chem.* **267**:17257-17263.
15. **Lin, X.L.**, Liu, M.T., and Tang, J. (1992) "Heterologous expression of thermopsin, a heat

- stable acid proteinase". *Enzyme Microb. Technol.* **14**:696-701.
16. Tang, J., Lin, Y., Co, E., Hartsuck, J.A., and **Lin, X.L.** (1992) "Understanding HIV protease: Can it be translated into effective therapy against AIDS?" *Scand. J. Clin. Lab. Invest.* **52**(210):127-135.
 17. **Lin, X.L.**, Dashti, A., Schinazi, R.F., and Tang, J. (1993) "Intracellular diversion of glycoprotein gp160 of human immunodeficiency virus to lysosomes as a strategy of AIDS gene therapy". *FASEB J.* **7**:1070-1080.
 18. **Lin, X.**, Loy, J.A., Sussman, F., and Tang, J. (1993) "Conformational instability of the N- and C-terminal lobes of porcine pepsin in neutral and alkaline solutions". *Prot. Sci.* **2**:1383-1390.
 19. **Lin, X.**, Tang, J., Koelsch, G., Monod, M., and Foundling, S. (1993) "Recombinant candidropsin, an extracellular aspartic protease from yeast *Candida tropicalis*". *J. Biol. Chem.* **268**:20143-20147.
 20. **Lin, X.**, Lin, Y., and Tang, J. (1994) "Relationships of human immunodeficiency virus protease with eukaryotic aspartic protease". *Methods Enzymol.* **241**:195-224.
 21. Tang, J., and **Lin, X.** (1994) "A new anti-HIV gene therapy strategy -- diversion of gp160 to lysosomes". *Int. Antiviral News* **2**:19-20.
 22. Tang, J., and **Lin, X.** (1994) "Engineering aspartic proteases to probe structure and function relationships". *Current Opinions in Biotechnology* **5**:422-427.
 23. Lin, Y.-Z., **Lin, X.**, Hong, L., Foundling, S., Heinrikson, R.L., Thaisrivongs, S., Leelamanit, W., Rateman, D., Shah, M., Dunn, B.M., and Tang, J. (1995) "Effect of point mutations on the kinetics and the inhibition of human immunodeficiency virus type 1 protease: relationship to drug resistance". *Biochemistry* **34**:1143-1152.
 24. **Lin, X.**, Koelsch, G., Loy, J., and Tang, J. (1995) "Rearranging the domains of pepsinogen". *Prot. Sci.* **4**:159-166.
 25. Rowell, J.F., Ruff, A.L., Guarnieri, F.G., Staveley-O'Carroll, K., **Lin, X.**, Tang, J., August, J.T., and Siliciano, R.F. (1995) "Lysosome-associated membrane protein-1-mediated targeting of the HIV-1 envelope protein to an endosomal/lysosomal compartment enhances its presentation to MHC class II-restricted T cells". *J. Immunol.* **155**:1818-1828.
 26. **Lin, X.**, and Tang, J. (1995) "Rearranging pepsinogen and pepsin by protein engineering". In: *Aspartic Proteinases: Structure, Function, Biology, and Biomedical Implications*, (Kenji Takahashi, ed.), Plenum Press, New York, pp 33-40.
 27. **Lin, X.**, and Tang, J. (1995) Thermopsin. *Methods Enzymol.* **248**:156-168.
 28. Ermolieff, J., **Lin, X.**, and Tang, J. (1997) Kinetic properties of saquinavir-resistant mutants of human immunodeficiency virus type 1 protease and their implications in drug resistance *in vivo*. *Biochemistry* **36**:12364-12370.

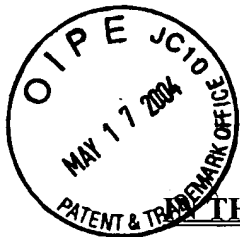
29. Reed, D.J., **Lin, X.**, Thomas, T.D., Birks, C.W., Tang, J., and Rother, R.P. (1997) "Alteration of glycosylation renders HIV sensitive to inactivation by normal human serum". *J. Immunol.* **159**:4356-4361.
30. Tang, J., and **Lin, X.** (1998) "Thermopsin". In: *Handbook of Proteolytic Enzymes*, A. (Barrett *et al.*, eds.), Academic Press, London, pp 980-982..
31. Ermolieff, J., **Lin, X.**, and Tang, J. (1998) "The effect of substrates on the kinetics and the *in vivo* threshold activity of mutant HIV-proteases". *Adv. Exptl. Med. & Biol.* **436**:47-51
32. Koelsch, G., Loy, J., **Lin, X.**, Tang, J. (1998) "Activation mechanism of pepsinogen as compared to the processing of HIV protease gag-pol precursor protein". *Adv. Exp. Med. Biol.* **436**:245-252.
33. Koelsch, G., Tang, J., Monod, M., Foundling, S.I., **Lin, X** (1998) "Primary substrate specificities of secreted aspartic proteases of *Candida albicans*". *Adv. Exp. Med. Biol.* **436**:335-338.
34. Faro, C., Ramalho-Santos, M, Verissimo, P., Pissarra, J., Frazao, C., Costa, J., **Lin X.L.**, Tang, J., Pires, E. (1998) "Structural and functional aspects of cardosins". *Adv. Exp. Med. Biol.* **436**:423-433.
35. Wang, X., **Lin, X.**, Lowy, J.A., Tang, J., Zhang, X.C. (1998) "Crystal structure of the catalytic domain of human plasmin complexed with streptokinase", *Science*. **281**:1662-1665.
36. **Lin, X.** (1998) "Construction of new retroviral producer cells from adenoviral and retroviral vectors". *Gene Therapy*. **5**:1251-1258.
37. Faro C, Ramalho-Santos M, Vieira M, Mendes A, Simoes I, Andrade R, Verissimo P, **Lin X**, Tang J, Pires E (1999) "Cloning and Characterization of cDNA Encoding Cardosin A, an RGD-containing Plant Aspartic Proteinase." *J Biol Chem* **274**(40):28724-28729
38. Wang, X., Jiang, L., Lei, Z., **Lin, X.** (1999) "The Experiment of HSV-tk Gene Therapy for Gastric Carcinoma *in vitro*." (Chinese) *Chinese Journal of Biochemistry and Molecular Biology*. **15**(6):983-986
39. Wang, X., Terzyan, S., Tang, J., Loy, J., **Lin, X.**, and Zhang, X. (2000) "Human plasminogen catalytic domain undergoes a novel conformational change upon activation" *J. Mol Biol.* **295**(4):903-914.
40. **Lin, X.**, Koelsch, G., Wu, S., Downs, D., Dashti, A., and Tang, J. (2000) "Human aspartic protease memapsin 2 cleaves the β -secretase site of β -amyloid precursor protein. *Proc Natl Aca Sci.* **97**(4):1456-1460
41. Ghosh, A. K., Shin, D., Downs, D., Koelsch, G., **Lin, X.**, Ermolieff, J., Tang, J. (2000) "Design of potent inhibitors form human brain memapsin 2 (β -secretase)" *J. Amer. Chem. Soc.*, **122**:3522-3523.

42. Koelsch, G., Tang, J., Loy, J.A., Monod, M., Jackson, K., Foundling, S.I., and **Lin, X.** (2000) "Enzyme characterization of secreted aspartic proteases of *Candida albicans*". *Biochimica et Biophysica Acta*, **1480**:117-131.
43. Hong L., Koelsch G., **Lin X.**, Wu S., Terzyan S., Ghosh A., Zhang X., Tang J. (2000) "Structure of Memapsin 2 (β -secretase) complexed with inhibitor: a template to design drugs for Alzheimer's Disease" *Science*, **290**:150-153.
44. Wang, X., Wu, S., Wei, X., **Lin, X.** (2000) "The cloning, expression, and refolding of TNF-related apoptosis inducing ligand" (Chinese). *Journal of Beijing Medical University*, **32**(5):387-390.
45. Wang, XJ, Wang, X., Wei, X., Lei, Z., **Lin, X.** (2000) "Construction of recombinant adenovirus (Ad-HSVtk) for tumor gene therapy" (Chinese). *China Science Abstract*, **6**(10):1274-1277.
46. Wang, XJ, Wang, X., Zhang, L., Wei, X., **Lin, X.** (2000) "Adenovirus-mediated gene therapy of human gastric carcinoma by Herpes Simplex Virus-thymidine kinase *in vitro*" (Chinese). *China Science Abstract*, **6**(10):1278-1281.
47. Wei, X., Wang, X., Zhang, L., Chen, K., Liang, Y., **Lin, X.** (2000) "The establishment and effect of Tet-regulated expression system of TRAIL on gastric carcinoma cell line" (Chinese). *China Science Abstract*, **6**(10):1282-1284.
48. Wei, X., **Lin, X.**, Wang, X. (2001) "TNF-related apoptosis inducing ligand and its research progress on cancer treatment" (Chinese). *Physiology Science Progress*, **32**(1):18-22.
49. Zhang, J., Wang, X., Zhang, L., Xu, J., Wang, XJ., **Lin, X.** (2001) "The anti-tumor effect of GM-CSF-tk fusion gene in human neuroblastoma cell line SH-SY5Y" (Chinese). *Journal of Peking University (Health Sciences)*, **33**(1): 62-65.
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51. Loy, A., **Lin, X.**, Schenone, M., Castellino, F.J., Zhang, X., and Tang, J. (2001) "Domain interactions between streptokinase and human plasminogen", *Biochemistry*. **4**;40(48):14686-95.
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53. Pan, Yujun, Peng, Z., Dashti, A., Wu, S., **Lin, X.**, Wu, M. (2002) "A Combined Delivery by Co-transduction of Adenoviral and Retroviral Vectors for Cancer Gene Therapy". *Cancer*

Abstracts and Presentations:

1. Tang, J., Wong, R.N.S., **Lin, X.L.**, Delaney, R., and Wang, X.-J. (1988) Molecular cloning and expression of aspartic protease zymogens. 18th Linderstrom-Lang Conference, Elsinore, Denmark.
2. **Lin, X.L.**, Wong, R., and Tang, J. (1988) cDNA Cloning, expression and site-directed mutagenesis of porcine pepsinogen in *Escherichia coli*. 14th International Congress of Biochemistry, Prague, Czechoslovakia.
3. **Lin, X.L.**, Wong, R.N.S., and Tang, J. (1988) Synthesis, refolding, purification, and mutagenesis studies of recombinant porcine pepsinogen. *J. Cell Biol.* 107:1051.
4. **Lin, X.L.**, Dashti, N., and Tang, J. (1989) Internal pH of the secretory granules in mouse pituitary AtT20 cells is above 5.0. The American Society for Cell Biology.
5. **Lin, X.L.**, Fusek, M., and Tang, J. (1989) Purification and cloning of a new heat stable acid protease, thermopsin, from *Sulfolobus acidocaldarius*. Mid-America Molecular & Cellular Biology Colloquium, Shangri-La, Afton, OK.
6. **Lin, X.L.**, Dashti, N., and Tang, J. (1990) Internal pH of the secretory granules in mouse pituitary AtT20 cells is above 5.0. American Society for Biochemistry and Molecular Biology.
7. **Lin, X.L.**, Fusek, M., and Tang, J. (1990) Thermopsin, a thermostable acid protease from *Sulfolobus acidocaldarius*. Aspartic Proteinase Conference, Sonoma County, California.
8. **Lin, X.**, and Tang, J. (1991) Expression and refolding of recombinant thermopsin. FASEB Meeting, Atlanta, Georgia, April, 1991.
9. **Lin, X.L.**, Dashti, A., Schinazi, R.F., and Tang, J. (1991) A new strategy for gene therapy against AIDS: Intracellular diversion of gp160 of HIV to lysosomes for degradation. Technical Resources, Inc.
10. **Lin, X.L.**, Dashti, A., Schinazi, R.F., and Tang, J. (1992) Intracellular diversion of envelope glycoprotein gp160 of human immunodeficiency virus to lysosomes for degradation. ASBMB.
11. **Lin, X.L.**, Lin, Y.Z., Koelsch, G., Gustchina, A., Wlodawer, A., and Tang, J. (1992) Two-chain pepsinogen heterodimer and homodimer: Models for comparisons to the aspartic protease of human immunodeficiency virus. ASBMB.
12. Bian, J.H., Tang, J., and **Lin, X.L.** (1993) Heterologous expression and purification of HIV-1 gag protein p17. ASBMB/DBC-ACS.
13. **Lin, X.L.**, and Tang, J. (1993) Alkaline inactivation of pepsin is due to denaturation of its N-Terminal lobe. ASBMB/DBC-ACS.

14. **Lin, X.** (1994) Structure and function of aspartic proteases. Lecturer and laboratory training, University of Coimbra, Portugal, May 23-June 6, 1994.
15. **Lin, X.,** and Tang, J. (1994) A new retrovirus-based *in vivo* gene delivery system. Technological Advances for Gene Therapy, Washington, D.C., Nov. 29-30, 1994.
16. Koelsch, G., Foundling, S., Tang, J., Loy, J., Monod, M., and **Lin, X.** Recombinant secretory aspartic proteases from *Candida albicans*. ASBMB/DBC-ACS Joint Meeting, San Francisco, CA, May 21-25, 1995.
17. Bian, J., **Lin, X.** and Tang, J. (1995) Nuclear translocation of HIV-1 matrix protein P17: the use of *Aequorea victoria* green fluorescence protein in protein tagging and tracing. ASBMNB/DBC/ACS, 1995.
18. Hong, L., Hartsuck, J.A., **Lin, X.**, Treharne, A., Foundling, S., and Tang, J. (1995) *In vitro* studies on the molecular basis of HIV protease mutants that resist inhibitors. Hovel HIV Therapies: From Discovery to Clinical Proof-of-Concept, Poster #32.
19. Koelsch, G., Tang, J., Monod, M., Foundling, S., and **Lin, X.** (1996) Primary substrate specificities of secreted aspartic proteases of *Candida albicans*. VIIth International Aspartic Proteinase Conference, Banff, Alberta, Canada, Oct. 22-27, 1996.
20. **Lin, X.**, and Tang, J. (1998) *In vivo* gene delivering producer cells constructed from adenoviral and retroviral vectors. Keystone Molecular and Cellular Biology Symposia (Molecular and Cellular Biology of Gene Therapy Conference), Keystone, CO, Jan. 19-25, 1998.
21. **Lin, X.** "Studies on human memapsins". Sept. 11, 1999. In: *The 8th International Conference on Aspartic Proteinases*", Funchal, Madeira, Portugal, Sept. 7-12, 1999. Organizing Committee Chairman: Dr. Carlos Faro, University of Coimbra, Portugal.
22. **Lin, X.** November 12, 1999. "Identification of memapsin 2 as the γ -secretase that processes the amyloid precursor protein: implications in the treatment of Alzheimer's Disease". College of Life Science, Peking University, Peking, China.



PATENT

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Broyles *et al.*

Serial No.: 10/003,669

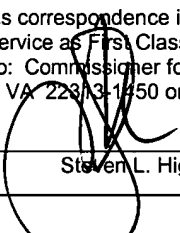
Filed: November 1, 2001

For: GENE REGULATION THERAPY
INVOLVING FERRITIN

Group Art Unit: 1632

Examiner: Janice Li Qian

Atty. Dkt. No.: OMRP:027US/SLH

CERTIFICATE OF MAILING 37 C.F.R. § 1.8	
I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date below:	
May 14, 2004 Date	 Steven L. Highlander

DECLARATION OF DR. JOHN McDONALD UNDER 37 C.F.R. §1.132

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

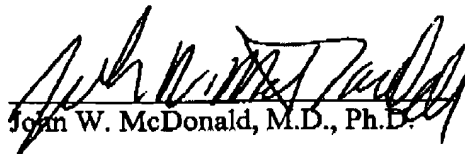
I, the undersigned, do declare that:

1. I am a citizen of the United States. I currently hold the position of Associate Professor at Washington University School of Medicine. I have over 12 years of research experience in the fields of medicine and neurology. A copy of my *curriculum vitae* is attached.

2. I am familiar with the work of Dr. Robert Broyles relating to ferritin-H as a repressor of the human β -globin gene in erythroid cells – when present in embryonic cells, it represses β -globin, but when absent in adult cells, β -globin is expressed. Thus, ferritin-H appears to be properly characterized as a hemoglobin switching factor.
3. Moreover, I am well aware of the implications this observation has in the treatment of β -globin-related diseases, such as sickle cell anemia. The relevant target cells for this condition (adult erythroid cells) have been shown to express ferritin receptors and to take up exogenously added ferritin protein, and other human cells (astrocytoma cells) which take up exogenous ferritin-H also transport it to the cell nucleus by an active transport mechanism. Thus, using ferritin-H or ferritin-H peptides as a therapeutic agent for treating sickle cell anemia is a logical extension of Dr. Broyles' work.
4. Regarding the feasibility of this approach, protein drugs have been used in clinical settings for several decades. For example, human insulin has been used to treat diabetics, and C-GSF has been used to treat infectious diseases and help to fight cancer. In addition, many other protein drugs have been approved by FDA in recent years. Thus, given what is known about the uptake and transport of ferritin-H, this protein is a promising candidate for treating indications such as sickle cell disease.

5. I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

05/13/04
Date


John W. McDonald, M.D., Ph.D.

CURRICULUM VITAE

John Wood McDonald III, M.D., Ph.D.

Birth Date: June 6, 1963

Social Security #: 348-66-0788

Business Address: Department of Neurology, Campus Box 8518
Section of Spinal Cord Injury Neurorehabilitation
Washington University School of Medicine
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E-mail: mcdonald@neuro.wustl.edu

Home Address: 4465 W Pine #20
St. Louis MO 63108
Tel (314) 534-4292

Academic Positions Held:

2001-present Medical Director,
Spinal Cord Injury Neurorehabilitative Unit
Rehabilitation Institute of St. Louis
St. Louis, MO

2003-present Associate Professor of Neurology, Neurological Surgery and
Neurobiology
Washington University School of Medicine
St. Louis, MO

2000-2003 Assistant Professor of Neurological Surgery
Washington University School of Medicine
St. Louis, MO

1998-present Assistant Professor of Neurology,
Barnes-Jewish Hospital
Washington University School of Medicine
St. Louis, MO

1998-present Section Head and Director, Spinal Cord Injury Neurorehabilitative
Unit Barnes-Jewish Hospital and
Washington University School of Medicine

St. Louis, MO

1996-1998 Instructor, Department of Neurology
Washington University School of Medicine
St. Louis, MO

Education:

1993-1996 Residency, Neurology
Barnes Hospital
Washington University School of Medicine
St. Louis, MO

1992-1993 Internship, Preliminary Medicine
St. Joseph Mercy Hospital
Ann Arbor, MI

1985-1992 M.D.
University of Michigan

1985-1992 Ph.D., Neurosciences
University of Michigan

1991-1992 Visiting Scientist
Darryle D. Schoepp, Ph.D.
Eli Lilly and Co.
Indianapolis, IN

1989-1990 Fellow, Neurology
Johns Hopkins University School of Medicine

1985 B.S., Liberal Arts and Science, Neurosciences,
University of Illinois, Champaign-Urbana

Honors and Awards:

St. Louis Business Journal's 40 under 40 Business Leaders in St. Louis for
outstanding contributions to their field and to the St. Louis Community, St. Louis
Business Journal, 2002

Medical Director of the Year, Rehabilitation Institute of St. Louis, HealthSouth, 2002

SCI Research Inspiration Award, Sam Schmidt Foundation, Las Vegas, Nevada, 2001

Reeve Research for Freedom Award, Gateway to a Cure, St. Louis, MO, 2000

Nominated one of Top Ten Physician in St. Louis, St. Louis Magazine, 2000

L.W. Freeman, M.D. Award for significant contributions to regenerative spinal cord research, National SCI Association, 1999

Mentored Clinical Scientist Development Award, National Institute of Health, 1996

Murray Goldstein Award, Neurotrauma Society, 1996

S. Weir Mitchell Award, American Academy of Neurology, 1996

Christopher Reeve Paralysis Foundation Research Consortium on Spinal Cord Injury, Consortium Member, 1995-1999

Fellowship, Medical Scientist Training Program, University of Michigan Medical School, 1985-1991

Magna cum laude in Neuroscience, University of Illinois, 1985

Phi Beta Kappa, University of Illinois, 1985

Golden Key National Honorary, University of Illinois, 1985

Phi Kappa Phi, University of Illinois, 1984

Membership in Professional Societies:

American Paraplegia Society, 2000-

Association of Academic Physiatrists, 2000-

American Spine Injury Association (ASIA), 2000-

National Spinal Cord Injury Association, 1999-

Association of Academic Physiatrists, 1999-

International Neurotrauma Society, 1996-

American Association for the Advancement of Science, 1994-

American Neurological Association, 1993-

American Academy of Neurology, 1993-

American Medical Association, Member, 1986-

Society for Neuroscience, Member, 1986-

Research and Clinical Interests:

Spinal cord injury: development of interventions to reduce injury, promote remyelination and enhance regeneration and recovery of function.

Biology of embryonic stem cells and neural progenitor cells.

Mechanisms of oligodendrocyte death: glutamate excitotoxicity.

Mechanisms regulating myelination.

Ontogeny of excitatory amino acid and related neurotransmitter pathways in the brain and their relationship to neurological disease.

Doctoral Thesis:

Co-Mentors: Drs. Michael V. Johnston, M.D. and Anne B. Young, M.D., Ph.D.

Title: Pharmacology and characterization of N-methyl-D-aspartate neurotoxicity in the developing central nervous system.

Symposiums Organized:

Spinal Cord Injury: From bench to bedside. Neuroanatomy Department Saturday Morning Seminar Series, Washington University School of Medicine, 1999.

Neurobiology: Physiologic and pathologic roles of excitatory amino acids during CNS development. Society for Neuroscience, St. Louis, MO, 1990; Lectures: J.W. Olney, M.P. Mattson, J.W. McDonald, H.T. Cline, M. Bear.

Invited Guest Lectures:

April 29-May 1, 2004 Breakfast seminar "Repairing the injured spinal cord: from stem cell to activity-based mechanisms of recovery" presentation and Dinner seminar "Repairing the CNS: from stem cell to activity-based therapies" **American Academy of Neurology Annual Meeting**, San Francisco, CA

April 14, 2004 “Classes Without Quizzes presentation of Repairing the damaged cord: from stem cell to activity-based mechanisms of recovery” at The Tower Club, Chicago, IL for **Chicago Washington University Club**, sponsored by Alumni Relations Washington University School of Medicine

April 13, 2004 “Repairing the damaged cord: from stem cell to activity-based mechanisms of recovery” presentation for the **Chicago Eliot Society** at the Standard Club, Chicago, IL for Annual Giving Washington University School of Medicine

March 29-April 1, 2004 “Repairing the damaged CNS: From stem cells to activity based therapies” **Royal College of Paediatrics and Child Health, 8th Spring Meeting, University of York, York UK**

March 25-26, 2004 “Repairing the damaged spinal cord: From stem cell to activity based mechanisms of recovery” presented at **The William Greenleaf Eliot Society of Kansas City** at Club 1000, Kansas City, MO for Alumni and Development Program Washington University School of Medicine

March 18-19, 2004 “Role of stem cells and repair of the damaged spinal cord presentation to the **BioTherapeutics Research Group, Robarts Research Institute**, London, Ontario, Canada and “Repairing the damaged cord: from stem cell to activity-based mechanisms of recovery” to **Parkwood Hospital SCI Program, Lawson Health Research Institute**, London, Ontario, Canada

March 4 and 5, 2004: “Repair of the damaged spinal cord: from stem cells to activity-based therapies”, “Setting up a clinical research team for comprehensive, life-long treatment approaches to spinal cord injury. **Northwest Neuroscience Symposium for Nurses and Other Allied Health Care Professionals, Eugene, Oregon**

February 10, 2004 Stars Program presentation of “Repair of the damaged spinal cord: from stem cell to activity based therapies” at the **University of Missouri St. Louis**.

January 17, 2004 “Repairing the damaged CNS: From stem cells to activity based therapies” **American Society for Peripheral Nerve, The Westin Mission Hills Resort, Palm Springs, CA**

December 8, 2003 “Activity-based rehabilitation for neurorecovery” **The Howard H. Steel Conference, Walt Disney World, Orlando, FL**

November 20, 2003 “Repairing the damaged CNS: From stem cells to activity based therapies” **University of Michigan Fall Short Course, Ann Arbor, MI**

November 18, 2003 “Spinal cord regeneration and repair and integration with the AutoAmbulator” **HealthSouth Medical Director’s Conference, Birmingham, AL**

November 13, 2003 “Stem Cells as Therapeutic Agents” **RUNN Course, Woods Hole, MA**

October 28, 2003 “Spinal cord injury and rehabilitation” **BJH Education Committee, Rehabilitation Staff, Barnes-Jewish Hospital, St. Louis, MO**

October 18-23, 2003 “Repair of the Damaged Cord; from Stem Cell to Activity-Based Recovery Programs” **Congress of Neurological Surgeons Meeting, Denver, Colorado**

October 10, 2003 “The Pathophysiology of Spinal Cord Injuries & Current Research in Activity Based Strategies for Improved Motor Function” **AAPM&R Meeting, Chicago, IL**

October 2, 2003 “Repairing the damaged cord; from stem cell to activity-based mechanisms of recovery” **Oklahoma Medical Research Foundation’s Work in Progress Seminar, Oklahoma**

September 14-16, 2003 “The Role of Embryonic Stem Cells in the Repair of the Damaged CNS” **Myelin Project Work Group, Acqui Terme, Italy**

September 10-11, 2003 “Repairing the damaged cord; from stem cell to activity-based mechanisms of recovery” **University of Toronto Program in Neuroscience, Toronto, Canada**

September 2, 2003 “Remyelination: Rationale for Phase-1 Human Trials Neurotransplantation in Spinal Cord Injury, **American Paraplegia Society, Las Vegas, Nevada**

August 14, 2003 “Repairing the damaged cord; from stem cell to activity-based mechanisms of recovery” **USCF Grand Rounds, San Francisco, CA**

August 9, 2003 “Strategies for Spinal Cord Repair After Spinal Cord Injury” **ASNR Workshop, Cleveland, OH**

July 17, 2003 “Development of a Restorative Treatment & Research Spinal Cord Injury Center; Building a Bench to Bedside Transitional System” **NSCIA 2003 Convention “Beyond All Barriers”, Chicago, IL**

July 2, 2003 “FES and neuroregeneration: Future convergence or divergence” **IFESS Conference, Noosa, Queensland, Australia**

June 12, 2003 “Recent Progress & Future Promise of Human Embryonic Stem Cells” **NIH Stem Cell Symposium, Bethesda, Maryland**

June 5, 2003 “Repairing the damaged cord: from stem cell to activity-based mechanisms of recovery” **Eliot Society Lecture Series, Atlanta, GA**

June 4, 2003 “Repairing the damaged cord: from stem cell to activity-based mechanisms of recovery” **Eliot Society Lecture Series, Washington, DC**

May 28, 2003 “Repairing the damaged cord: from stem cell to activity-based mechanisms of recovery”. **Eliot Society Lecture Series, Seattle, WA**

May 27, 2003 “Repairing the damaged cord: from stem cell to activity-based mechanisms of recovery”. **Eliot Society Lecture Series, Denver, CO**

May 9, 2003 “Repairing the Damaged Cord: From Stem Cell to Activity-based Mechanisms of Recovery” **Brookhaven National Laboratory Medical Department, Long Island, NY**

May 5, 2003 “Repairing the Damaged CNS: From Embryonic Stem Cell transplantation to Mobilizing Endogenous Stem Cells” **National Organization of Presbyterians, St. Louis, MO**

April 24, 2003 “Repairing the Damaged CNS: From Stem Cells to Activity-dependent Processes” **Life Sciences Speaker Series, Washington University, St. Louis, MO**

March 31, 2003 “Very Late Recovery Following Spinal Cord Injury: Extension of Evaluation and Outcomes” **2003 AAN Meeting, Honolulu, Hawaii**

March 8, 2003 “Repairing the Damaged Cord: From Stem Cell to Activity-based Mechanisms of Recovery” **St. Louis, MO**

February 26, 2003 “The Possibilities of Nervous System Repair” **Naples Salon, Naples, Florida**

February 7, 2003 “Repairing the Damaged Cord: From Stem Cell to Activity-based Mechanisms of Recovery”, **Millikin University, Decatur, IL**

February 3, 2003 **NIH/NINDS Spinal Cord Injury Therapy Workshop, Bethesda, Maryland**

January 29, 2003 “Repairing the Damaged Cord: From Stem Cell to Activity-based Mechanisms of Recovery” **Albany Medical College’s Neuroscience Grand Rounds, Albany, New York**

December 8, 2002 “Repair of the Damaged CNS” **Jewish Hospital College of Nursing and Allied Health, St. Louis, MO**

December 3, 2002 “Repairing the Damaged Spinal Cord: From Stem Cells to Activity-Based Treatments” **3rd Asia Pacific Symposium, Sheraton Perth, Western Australia**

November 21, 2002 “Advances in Neurological Rehabilitation” **Washington University School of Medicine Mini-Med School Presentation, St. Louis, MO**

November 19, 2002 “Promising Strategies to Repair the Damaged Spinal Cord” **STARS Program (Student and Teachers as Research Scientist) UMSL, St. Louis, MO**

November 14, 2002 “Repairing the Damaged Spinal Cord: from stem cells activity-based treatments” **2002 SCI Educational Conference, Phoenix, Arizona**

November 8, 2002 “Repairing Damaged CNS (Central Nervous System): role of stem cells and activity” **The Myelin Project Work Group, Bal Harbor, Florida**

November 2, 2002 “Neural Transplantation & Activity-Based Recovery” & “Clinical Trials of Intervention for SCI” **Clinical Trials in Medical Rehabilitation Conference- (Kessler Institute), Parsippany, New Jersey**

October 31, 2002 “Stem Cells as Therapeutic Agents” **RUNN Course, Woods Hole, Massachusetts**

October 26, 2002 “Advances in Neurological Rehabilitation; applicability to ALS patients” **ALS Project Hope, St. Louis, MO**

October 18, 2002 “Repairing the Damaged Spinal Cord: from stem cells to activity based recovery programs” **American Academy of Neurological Surgery Annual Meeting, Scottsdale, Arizona**

September 19, 2002 “Repair of the Damaged CNS: the spinal cord injury example” **Internal Medicine Grand Rounds, Washington University School of Medicine, St. Louis, MO**

September 12, 2002 “CNS Repair: What is Do-able” **AACPDM, New Orleans, Louisiana**

September 7, 2002 “Repairing the Damaged Spinal Cord” **Hendrick Medical Center Fall Symposium, Aboline, Texas**

August 7, 2002 “Spinal Cord Injury”, **Summer Stock Lecture Series, Washington University School of Medicine, St. Louis, MO**

August 7, 2002 “Spinal Cord Injury Update”, **Barnes-Jewish Hospital Patient Care Leadership, St. Louis, MO**

June 15, 2002 “Stem Cell Research”, **Missouri Pharmacy Association Convention, Lake of the Ozarks, MO**

June 7, 2002 “Cell Transplantation for Spinal Cord Injury Repair”, **17th Annual Lehman Symposium, Seattle, WA**

June 6, 2002 “Repairing the Damaged Cord: From activity-based restoration to stem cell transplantation”, **Northwest Regional SCI Research Forum, Seattle, WA**

June 4, 2002 “Advances in Neurological Rehabilitation and the Treatment of Spinal Cord Injury”, **Washington University School of Medicine’s Mini-Med School for the Coalition for Plant and Life Sciences, St. Louis, MO**

May 26-30, 2002 “Therapeutic Applications of Stem Cells”, **International Healthcare Trip, Geneva, Switzerland**

May 21, 2002 “Repairing the Damaged Spinal Cord”, **Missouri Head Injury Advisory Council Conference, Jefferson City, MO**

May 16, 2002 “Repairing the Damaged Spinal Cord”, **Reunion Scientific Program: Medical Update ’02, St. Louis, MO**

April 29, 2002 “What are the limits for self-repair in the injured adult CNS?”, **Neurology & Neurosurgery Research Seminar, St. Louis, MO**

April 19, 2002 “Stem Cells and Repair of the Injured CNS”, **MSP Research Symposium, Urbana, IL**

April 14, 2002 “Future of Spinal Cord Injury: Therapy based on Neural Repair and Gait Retraining, **2002 AAN Meeting, Denver, CO**

April 9, 2002 “Repairing the Damaged Spinal Cord; ES Cells and Remyelination” **Niagara County Community College, San Born, NY**

April 6, 2002 “Restoring function after spinal cord injury” **John Hopkins Board of Trustee Retreat, Baltimore, MD**

April 2, 2002 “Spinal Cord Injury In-Service” **Spinal Cord Presentation to Healthlink, St. Louis, MO**

March 18, 2002 “Education In-service” **The Rehabilitation Institute of St. Louis, St. Louis, MO**

March 15, 2002 “Repairing the Damaged Spinal Cord: Early Experience with Embryonic Stem Cell Transplantation” **13th Annual Spring Brain Conference, Sedona, AZ**

March 11, 2002 “Repairing the Damaged Spinal Cord; ES Cell Transplantation”, **The New York Academy of Medicine, New York, NY**

February 2, 2002 “Stem Cell Research”, **Saturday Scholar Program, Belleville, IL**

January 14, 2002 “Repairing the Damaged Spinal Cord”, **Washington University School of Medicine OT Program, St. Louis, MO**

January 28, 2002 “Stem Cells and Repair of the Damaged CNS: From Scientific Tools to Applied Therapies”, **John Hopkins Hospital “Special Seminar”, Baltimore, MD**

January 23, 2002 “New Concepts in CNS Injury Repair”, **Washington University School of Medicine Neurosurgery Grand Rounds, St. Louis, MO**

January 14, 2002 “Repairing the Damaged Spinal Cord”, **Washington University School of Medicine OT Presentation to Faculty & Students, St. Louis, MO**

December 17, 2001 “Embryonic Stem Cells..from Scientific Tools to Applied Therapies”, **Stanford University, Stanford, CA**

December 15, 2001 “Stem Cells: From Beginnings to Clinical Trials”, **9th International Symposium on Neural Regeneration (ISNR), Pacific Grove, CA**

December 11, 2001 “Repairing the Damaged Spinal Cord: Embryonic Stem Cell Transplantation”, **Washington University School of Medicine Emergency Medicine Grand Rounds**

December 7, 2001 “Neural Stem Cells in Development and Regeneration”, **NIAAA Stem Cell Meeting, Bethesda, MD**

November 1, 2001 “Spinal Cord Injury Repair: Doable Therapeutics”, **Keynote Speaker, 2001 Shepherd Center’s Virginia C. Crawford Annual Research Symposium, Shepherd Center, Atlanta, Georgia.**

October 26, 2001 “Stem Cells as Therapeutic Agents”, **RUNN, Wood Hole, Massachusetts**

October 18, 2001 “Advances in Neurological Rehabilitation”, **Washington University School of Medicine Mini-Med School Presentation, St. Louis, MO**

October 17, 2001 “Stem Cell Research and How It Applies to Other Diseases”, **Grace Episcopal Church, St. Louis, MO**

October 15, 2001 “Stem Cell Research, What’s happening on the frontier of research”, **S. Carolina Workers” Compensation Educational Conference, Myrtle Beach, South Carolina.**

October 9, 2001 “Regeneration Strategies for the Patient with Spinal Cord Injury” and “Functional Stimulation & Reactivation of the Locomotor Center” **Shriners Hospital for Children, Philadelphia, PA**

September 29, 2001 “Embryonic Stem Cells”, **12th Annual Meeting of “The Myelin Project Work Group”, Paris, France**

September 27, 2001 “Repairing the Damaged Spinal Cord: Doable Therapeutics”, **Johns Hopkins Hospital “Grand Rounds”**

August 1, 2001 “Spinal Cord Regeneration”, **Department of Veterans Affairs Spinal Cord Injury Service Grand Rounds, St. Louis, MO**

July 13, 2001 “Embryonal Stem Cells Promote Functional Recovery in Spinal Injured Animals”, **2nd International Transverse Myelitis Symposium, Baltimore, Maryland**

July 6, 2001 “Spinal Cord Injury Research”, **HHMI Summer Seminar, St. Louis, MO**

June 17, 2001 “Neural Repair and Functional Restoration Workshop-Bridging the Gap”, **IFESS 2001, Cleveland, Ohio**

June 16, 2001 “ES Grafts in Spinal Cord Injury”, **2001 Kentucky Spinal Cord & Head Injury Research Trust Symposium, Louisville, KY**

May 20, 2001 “Repairing the Damaged Cord”, **ASIA, Long Beach, California.**

May 6, 2001 “Repairing the Damaged Spinal Cord: What is Doable?”, **XXIII International Symposium, Montreal, Canada**

May 7, 2001 “Mechanisms of Spinal Cord Recovery after Injury”, **AAN, Philadelphia, PA**

April 27, 2001 “2001 Michael J. Ellis Distinguished Lecture on Disability Science & Practice” **University of Illinois, Champaign, IL**

April 11, 2001 “Repairing the Damaged Spinal Cord: Doable Therapeutics and Development of a World Class Spinal Cord Injury Center”, **Clayton Rotary, St. Louis, MO**

April 7, 2001 “Spinal Cord Regeneration”, **Central Society of PM&R Meeting, St. Louis, MO**

April 2, 2001 “Embryonic Stem Cells and Repair of the Damaged Spinal Cord” **American Association of Anatomy, Orlando, Florida**

March 30, 2001 “Embryonic Stem Cell Differentiation in Oligodendrocytes” 1st **International Symposium on Clinical Use of Cellular Products, Regensburg, Germany**

March 8, 2001 “Repair of the Injured CNS: Promoting Oligodendrocytes Remyelination, **Spring Brain Conference, Sedona, Arizona**

March 4, 2001 “Research in Spinal Cord Injury”, **Washington University School of Medicine PM&R Presentation, St. Louis, MO**

February 9, 2001 “Spinal Cord Trauma”, **Trends in Trauma Conference, St. Louis, MO**

February 5, 2001 “Spinal Cord Injury”, **Washington University School of Medicine 2nd Year Medical School Course, Diseases of the Nervous System”, St. Louis, MO**

January 27, 2001 “Repair of the Damaged Spinal Cord”, **Nasser Institute, Cairo, Egypt.**

January 23, 2001 “Advances in Spinal Cord Injury Rehabilitation: Scientific Basis of Activity-Dependent Rehabilitation”, **Nasser Institute, Cairo, Egypt.**

January 12, 2001 “Regeneration in the context of FES”, **Shriners Hospital, Philadelphia, PA.**

November 28, 2000 “Stem Cells and CNS Repair: What is Doable?” Department of Immunology and Oncology, National Center of Biotechnology, **Madrid, Spain.**

November 3, 2000 “Stem Cell Transplantation”, Session V: How can the brain and spinal cord be repaired. 18th Annual National Neurotrauma Society Symposium, **New Orleans, Louisiana.**

October 20, 2000 “CNS Repair: Stem cell therapies”, Research Updated in Neurobiology and Neurosurgeons (RUNN) 2000, **Woods Hole, Massachusetts.**

September 23, 2000 “Activity-Dependent Rehabilitation”, SJ Rose Symposium, Program for Physical Therapy, **Washington University, St. Louis, Missouri.**

September 12, 2000 “ES cells and Repair of the Damaged Nervous System”, **Ataxia-Telangiectasia Foundation, San Diego, California.**

August 4, 2000 “Repairing the Damaged Spinal Cord”, 14th Annual Combined Clinical Conference on Emergency Care, **Lake of the Ozarks, MO.**

July 28, 2000 “ES cells, Remyelination and Recovery of Function”, **Geron Corporation, San Francisco, California.**

July 19, 2000 “Repairing the Damaged Spinal Cord”, **Orthopaedics Grand Rounds, Department of Orthopaedics, Washington University School of Medicine, St. Louis, Missouri.**

July 13, 2000 “Animal Models of Spinal Cord Injury as Paradigms for Stem Cell Therapy”, **Food and Drug Administration, Center for Biologics Evaluation and Research, Biological Response Modifiers Advisory Committee, Gaithersburg, Maryland.**

July 5, 2000 “AMPA- Receptor Mediated Excitotoxicity Contributes to the Selective Loss of Oligodendrocytes in Central Pontine Myelinolysis”, **Anesthesia Grand Rounds, Department of Orthopaedics, Washington University School of Medicine, St. Louis, Missouri.**

June 28, 2000 “Spinal Cord Injury- What is Doable?”, **AACD, Spinal Cord Injury Center, Sao Paulo, Brazil.**

June 25, 2000 “Developing a World Class Spinal Cord Injury Program”, **Assetta, Tatui, Brazil.**

June 10, 2000 “Embryonic Stem (ES) Cells as a Tool and Strategy to Repair the Damaged Nervous System”, **Second Hershey Conference- Cerebral Blood Flow and Metabolism, Hotel Hershey, Hershey, Pennsylvania.**

April 5, 2000 “Spinal Cord Injury- What is doable?; an ES cell transplantation approach”, **Neuroscience Lecture Series, Columbia University, Columbia, Missouri.**

March 29, 2000 “Mechanisms of Spinal Cord Injury. Methods of Repair- What is Doable?”, **Department of Neuroradiology, National Institute of Health, Bethesda, Maryland.**

March 5-8, 2000 “SCI Think Tank”, **Kent Waldrep National Paralysis Foundation (KWNPF), Dallas, Texas.**

January 14, 2000 “Mechanisms of SCI & methods of repair- What is doable?” **Neuroscience Lecture Series, Lexington, Kentucky.**

December 10, 1999 “Mechanisms of SCI & methods of repair- Where do neuroregeneration and neural prostheses meet?” **Neural Prosthesis Seminar, Cleveland FES Center, Case Western Reserve University and MetroHealth Medical Center, Cleveland Ohio.**

December 7, 1999 “Embryonic stem cell transplantation: A strategy for repairing the injured spinal cord.” **Advances in Embryonic Stem Cell and Nuclear Transfer**

Technologies, Asilomar Conference Grounds, Pacific Grove, California. Sponsored by Geron Corporation.

University and Hospital Committee Memberships

2001 -	PNT Committee (Pharmacy & Therapeutics), Rehabilitation Institute of St. Louis
2001- Present	Neurology Executive Committee, Department of Neurology
2001- Present	Medical Executive Committee, Rehabilitation Institute of St. Louis
1999- 2000	Development Committee, Rehabilitation Institute of St. Louis
1998	Occupational Therapy Doctoral Program Steering and Development Committee
1998- 2000	Executive Rehabilitation Committee
1999- Present	Rehabilitation Policy Review Committee

Teaching Responsibilities:

a. Clinical Fellows:

Cristina Sadowsky, M.D., Spinal Cord Injury Medicine Fellow, 1998-1999

Ramani Gadi, M.D., Spinal Cord Injury Medicine Fellow, 2000-2001

Tan Fung, M.D., Spinal Cord Injury Medicine Fellow, 2001-2002

b. Research Fellows:

Yun Qu, M.D., Research Post-doctoral Fellow, 1996-

Mike Howard, Ph.D., Research Post-doctoral Fellow, 1998-

Dan Kadunce, Ph.D., Research Post-doctoral Fellow, 1998-2000

Su Liu, M.D., Ph.D., Research Post-doctoral Fellow, 1998-

Todd Stewart, M.D., Neurosurgery Resident Research Fellow, 1999-2001

Shovan Chakraborty, M.D., Ph.D., Senior Research Fellow, 1999-2000

James Lu, M.D., Neurosurgery Resident Research Fellow, 1999-

Qun Li, Ph.D., Research Post-doctoral Fellow, 2000-

Daniel Becker, M.D., Ph.D., Research Post-doctoral Fellow, 2001-

Husan Ao, M.D., Research Post-doctoral Fellow, 2001-

Ephron Rosenzweig, Research Post-doctoral Fellow, 2003-

David Lenihan, Research Post-doctoral Fellow, 2003

Li Lin, Research Post-doctoral Fellow, 2003

c. Courses and Lectures:

Medical School, presentation to 2nd year students, February 1999, 2000, 2001
Diseases of the Nervous System
“Spinal Cord Injury”

Spring Saturday Seminar Series, Dept. of Anatomy and Neurobiology, April-June
1999
“Spinal Cord Injury: from bench to bedside”
Organized 11 speaker series on SCI, prevention and repair

Bedside and Didactic Teaching:

Neurology Residents

Physical Medicine and Rehabilitation Residents

Medical Students- “Neurologic Assessment”, 2nd year medical students

Editorial Referee Responsibilities:

Brain Research
Brain Research Reviews
Experimental Neurology
Journal of Neuroscience
Journal of Neurotrauma
Glia
Lancet
Nature Biotechnology
Nature Medicine
Pediatric Research
Proceedings of the National Academy of Sciences

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Grant Review Responsibilities:

NIH Cell Transplant Special Review, Santa Fe New Mexico, February 21-22, 2001

New Jersey Spinal Cord Injury Foundation, Review Panel Member, 2001-present

Special Emphasis Panel Review, Washington, D.C. (NINDS), March 13, 2001

New York State Spinal Cord Injury Foundation, Review Panel Member, 2000- present

National Institutes of Health, NINDS, Special Reviewer, 2000-

Paralyzed Veterans of America Spinal Cord Research Foundation, Regular reviewer, 1997- present

International Spinal Cord Research Foundation, 1999- present

Research Grant and Funding Sources:

Active Research Support

Governmental

1R29 NS37927-03	7/1/98-6/30/03	Principle Investigator
CSR/NIH	\$83,995 Annual Direct	
Mechanism of Oligodendrocyte Death in Spinal Cord Injury		
P01 NS39577-01	12/01/99- 11/30/04	Principle Investigator P3
NIH-NINDS	\$141,088 Annual Direct	
ES Cell Transplantation After Spinal Cord Injury: Project 3- Survival and Differentiation of ESNLCs After Transplantation		
P01 DE07734-15	04/01/00- 03/31/05	Principle Investigator P4
NIH-NIDCR	\$132,682 Annual Direct	
Mechanisms of Damage Induced Trigeminal Reorganization: Project 4- Neurotrophin Control of Thalamocortical Development		
1 RO1 NS 40520-01	09/27/00-09/26/03	Principle Investigator
NIH-NINDS	\$250,000 Annual Direct	
ES Cell Myelination in Injured Spinal Cord		

b. Non-Governmental

Sam Schmidt Foundation 01/01/02-01/01/03 Principle Investigator
\$50,000 Annual Direct
Human Embryonic Stem Cells: Moving from Bench to Bedside

Past Research Support (Federal and non-Gov.):

5 K08 NS01931-04 12/01/96-11/30/2000 Principle Investigator
NIH-NINDS \$85,000 Annual Direct
AMPA Receptor Mediated Spinal Cord Oligodendrocyte Death

R01 NS36265 9/15/97-9/14/2000 Co-Investigator
NINDS/NIH \$ 25,000 annual direct
Oligodendrocyte death in cerebral ischemia
The major goals of this project are to examine the role of excitotoxic oligodendrocyte death in cerebral ischemia.

SCI STATeam Program Grant 4/1/99- 3/31/01 Principle Investigator
Barnes-Jewish Hospital Foundation \$120,000 Annual Direct
STATeam Clinical Care Pathway Implementation and Benefits

KECK Grant 7/1/99- 6/30/00 Co-Investigator
Keck Foundation \$ 990,000 Annual Direct
Transplantation of Embryonic Stem Cells in the Injured Spinal Cord

Group Health Grant 10/1/99- 9/31/99 Principle Investigator
Group Health Foundation \$ 30,000 Annual Direct
STATeam Clinical Care Pathway Implementation and Benefits

Clinical Trials Engaged:

Porcine Fetal Cell Transplantation Principle Investigator
Phase I, Porcine Fetal Spinal Cord Cells Treated with Anti-MHC Class I Antibody for Spinal Cord Repair.
Diacrin, Inc.

Clinical Trials Completed:

Fampridine-SR in SCI: SCI-F201 Principle Investigator
Phase II, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate Safety and Efficacy of Oral Fampridine-SR in Subjects with Chronic, Incomplete Spinal Cord Injury.
Acorda Therapeutics, Inc.

Neurotrophin-3 in SCI Principle Investigator
Phase III, Double-Blind, Placebo-Controlled, Cross-Over Study to Evaluate the Efficacy
of Subcutaneous Neurotrophin-3 in Subjects with Chronic Spinal Cord Injury.
Regeneron, Inc.

Advisory Board Memberships:

2003- present Chairman, Spinal Cord Injury Research Program Advisory Board,
University of Missouri at Columbia, Missouri

2001- present Scientific Advisory Board, New York State SCI Research Board, NY, NY.

2000- Present Research Advisory Board Member, Shriners Hospital, Philadelphia, PA

1999- Present Advisory Board Member, Gateway to a Cure, St. Louis, MO

National / Governmental Committees and Responsibilities:

Auxiliary Awards Committee, American Academy of Neurology, 2001- Present.

Special Governmental Consultant, Food and Drug Administration Advisory Committee
Consultant, Biological Response Modifiers Advisory Committee Meeting #27, Human
Stem Cells as Cellular Replacement Therapies for Neurological Disorders, Hilton Hotel,
Gaithersburg, Maryland, July 13-14, 2000.

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Publications in Scientific Journals

1. Greenough WT, **McDonald JW**, Parnisari RM and Camel JE. Environmental conditions modulate degeneration and new dendrite growth in cerebellum of senescent rats. Brain Res. 380: 136-143, 1986.
2. **McDonald JW**, Silverstein FS and Johnston MV. MK-801 protects the neo-natal brain from hypoxic-ischemic damage. Eur. J. Pharmacol. 140: 359-361, 1987.
3. **McDonald JW**, Silverstein FS and Johnston MV. Neurotoxicity of N-methyl-D-aspartate is markedly enhanced in developing rat central nervous system. Brain Res. 459: 200-203, 1988.
4. **McDonald JW**, Silverstein FS and Johnston MV. Neuroprotective effects of MK-801, TCP, PCP and CPP against N-methyl-D-aspartate induced neurotoxicity in an in vivo perinatal rat model. Brain Res. 490: 33-40, 1989.
5. **McDonald JW**, Cline HT, Constantine-Paton M, Maragos WF, Johnston MV and Young AB. Quantitative autoradiographic localization of NMDA, quisqualate and PCP receptors in frog tectum. Brain Res. 482: 155-158, 1989.
6. **McDonald JW**, Silverstein FS, Cardona D, Hudson C, Chen R and Johnston MV. Systemic administration of MK-801 protects against N-methyl-D-aspartate and quisqualate mediated neurotoxicity in perinatal rats. Neurosci. 36: 589-599, 1990.
7. **McDonald JW**, Penney, Jr. JB, Johnston MV and Young AB. Characterization and regional distribution of strychnine-insensitive [³H]glycine binding sites in rat brain by quantitative receptor autoradiography. Neurosci. 35(3): 653-668, 1990.
8. **McDonald JW**, Uckele J, Silverstein FS and Johnston MV. HA-966 (1-Hydroxy-3-aminopyrrolidone-2) selectively reduces N-methyl-D-aspartate (NMDA)-mediated brain damage. Neurosci. Letts. 104:167-170, 1989.
9. **McDonald JW**, Roeser NF, Silverstein FS and Johnston MV. Quantitative assessment of neuroprotection against NMDA-mediated brain injury. Exp. Neurol. 106: 289-296, 1989.
10. **McDonald JW**, Silverstein FS and Johnston MV. MK-801 pretreatment enhances NMDA-mediated brain injury and increases brain NMDA recognition site binding in rats. Neurosci. 38: 103-113, 1990.

11. Uckele JE, **McDonald JW**, Johnston MV and Silverstein FS. Effect of glycine and glycine receptor antagonists on NMDA-induced brain injury. Neurosci. Letts. 107: 279-283, 1989.
12. Silverstein FS, **McDonald JW**, Bomarrito M and Johnston MV. Effects of hypoxia-ischemia and MK-801 treatment on the binding of a phencyclidine analogue in the developing brain. Stroke 21(3): 310-315, 1990.
13. **McDonald JW**, Silverstein FS and Johnston MV. Magnesium reduces N-methyl-D-Aspartate (NMDA)-mediated brain injury in perinatal rats. Neurosci. Letts. 109: 234-238, 1990.
14. **McDonald JW** and Johnston MV. Non-ketotic hyperglycinemia: pathophysiological role of N-methyl-D-aspartate type excitatory amino acid receptors. Annals Neurol. (letter) 27(4): 449-450, 1990.
15. **McDonald JW**, Johnston MV and Young AB. Differential ontogenic expression of three receptors comprising the NMDA receptor/channel complex in the rat hippocampus. Exp. Neurol. 110: 237-247, 1990.
16. **McDonald JW** and Johnston MV. Physiological and pathophysiological roles of excitatory amino acids during central nervous system development. Brain Res. Rev. 15(1): 41-70, 1990.
17. **McDonald JW** and Johnston MV. Pharmacology of N-methyl-D-aspartate induced brain injury in an in vivo perinatal rat model. Synapse 6: 179-188, 1990.
18. **McDonald JW**, Trescher WH and Johnston MV. The selective ionotropic-type quisqualate receptor agonist AMPA is a potent neurotoxin in immature brain. Brain Res. 526: 165-168, 1990.
19. Hu B, **McDonald JW**, Johnston MV and Silverstein FS. Excitotoxic brain injury suppresses striatal high affinity glutamate uptake in perinatal rats. J. Neurochem. 56: 933-937, 1991.
20. **McDonald JW**, Chen C-K, Trescher WH and Johnston MV. Effect of body temperature on the severity of excitotoxic brain injury in perinatal rats. Neurosci. Letts. 126: 83-86, 1991.
21. **McDonald JW**, Garofalo EA, Hood T, Sackellares JC, Gilman S, McKeever PE, Troncoso J and Johnston MV. Altered excitatory and inhibitory amino acid receptor binding in hippocampus of patients with temporal lobe epilepsy. Annals Neurol. 29: 529-541, 1991.

22. Debski EA, Cline HT, **McDonald JW**, Constantine-Paton M. Chronic application of NMDA decreases the NMDA sensitivity of the evoked tectal potential in the frog. J. Neurosci. 11: 2947-2957, 1991.
23. Schoepp DD, Johnson BG, Salhoff CR, **McDonald JW** and Johnston MV. In vitro and in vivo pharmacology of trans- and cis-ACPD: dissociation of metabotropic and ionotropic excitatory amino acid receptor effects. J. Neurochem. 56: 1789-1799, 1991.
24. **McDonald JW**, Trescher WH and Johnston MV. Susceptibility of brain to AMPA and quisqualate excitotoxicity transiently peaks during early postnatal development. Brain Res. 583: 54-70, 1992.
25. Hamosh A, **McDonald JW**, Valle D, Francomano CA, Niedermeyer E and Johnston MV. Experience with dextromethorphan and high dose benzoate therapy in an infant with non-ketotic hyperglycinemia. J. Pediatr. 121: 131-135, 1992.
26. **McDonald JW** and Schoepp DD. The metabotropic excitatory amino acid receptor agonist 1S,3R-ACPD selectively potentiates NMDA induced brain injury. Eur. J. Pharmacol. 215: 353-354, 1992.
27. **McDonald JW** and Johnston MV. Neuroprotective synergism of 2-amino-3-phosphonopropionate (D,L-AP3) and MK-801 against ibotenate induced brain injury. Neurosci. Letts. 145: 213-216, 1992.
28. **McDonald JW** and Schoepp DD. Aminooxyacetic acid produces excitotoxic brain injury in neonatal rats. Brain Res. 624: 239-244, 1993.
29. **McDonald JW**, Fix AS, Tizzano JP and Schoepp DD. Seizures and brain injury in neonatal rats induced by 1S,3R-ACPD, a metabotropic glutamate receptor agonist. J. Neurosci. 13: 4445-4455, 1993.
30. Schoepp DD, Lunn WHW, Salhoff CR and **McDonald JW**. The NMDA receptor agonist DL-(tetrazol-5-yl) glycine is a highly potent excitotoxin. Eur. J. Pharmacol. 270: 67-72, 1994.
31. Cline HT, **McDonald JW** and Constantine-Paton M. Glutamate receptor binding in juvenile and adult *Rana pipiens* CNS. J. Neurobiol. 25: 488-502, 1994.
32. Wright RA, **McDonald JW** and Schoepp DD. Distribution and ontogeny of 1S,3R-ACPD-sensitive and quisqualate-insensitive 3H-glutamate binding sites in the rat brain. J. Neurochem. 63: 938-945, 1994.
33. Trescher WH, **McDonald JW** and Johnston MV. Quinolinate-induced injury is enhanced in developing brain. Dev. Brain Res. 83: 224-232, 1994.

34. **McDonald JW**, Bautista RW and Gutmann DH. Pseudo-cervical cord syndrome: a deceptive flumazenil-reversible manifestation of hepatic encephalopathy. Archives Neurol. (letter) 53: 956, 1996.
35. **McDonald JW**, Goldberg MP, Gwag BJ, Chi S-I and Choi DW. Cyclosporine induces neuronal apoptosis and selective oligodendrocyte death in cortical cultures. Annals Neurol. 40: 750-758, 1996.
36. Choi DW, Goldberg MP and **McDonald JW**. Cyclosporine induces neuronal apoptosis and selective oligodendrocyte death in cortical cultures; Reply to Dr. Windebank. Annals Neurol. 41: 563-564, 1997.
37. **McDonald JW**, Behrens MI, Chung C, Bhattacharyya T and Choi DW. Susceptibility to apoptosis is enhanced in immature cortical neurons. Brain Res. 759: 228-232, 1997.
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39. **McDonald JW**, Shapiro SM, Silverstein FS and Johnston MV. Role of glutamate mediated excitotoxicity in bilirubin-induced brain injury in the Gunn rat model. Exp. Neurol. 150: 21-29, 1998.
40. **McDonald JW**, Althomsons SP, Hyrc KL, Choi DW and Goldberg MP. Oligodendrocytes are highly vulnerable to AMPA/kainate receptor-mediated excitotoxicity. Nature Med. 4: 291-297, 1998.
41. **McDonald JW**, Bhattacharyya T, Sensi SL, Lobner D, Ying HS, Canzoniero LMT and Choi DW. Extracellular acidity potentiates AMPA receptor-mediated cortical neuronal death. J. Neurosci. 18: 6290-6299, 1998.
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43. **McDonald JW**. Repairing the damaged spinal cord. Scientific American, 281(3): 64-73, 1999.
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46. Liu S, Qu Y, Stewart T, Howard M, Chakraborty S, Holekamp T, **McDonald JW**. Embryonic stem cells differentiate into oligodendrocytes and myelinate in culture and after spinal cord transplantation. Proceedings of the National Academy of Sciences, 97: 6126-6131, 2000.
47. Grill WM, **McDonald JW**, Peckham PH, Heetderks W, Kocsis J, Weinrich M. At the interface: Convergence of neural regeneration and neural prostheses for restoration of function. J. Rehabilitation Research and Development, 38: 633-639, 2001.
48. Corbetta M, Burton H, Sinclair RJ, Conturo TE, Akbudak E, **McDonald JW**. Functional reorganization and stability of somatosensory-motor cortical topography in a tetraplegic subject with late recovery. Proceed of the Nat Acad of Sciences of the United States of America. 99(26): 17066-71, 2002.
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50. Sadowsky C, Volshteyn O, Schultz L, **McDonald JW**. Spinal Cord Injury. Disability & Rehabilitation, 24(13): 680-687, 2002.
51. **McDonald JW**, Becker D, Sadowsky CL, Jane JA Sr, Conturo TE, Schultz LM. Late Recovery following Spinal Cord Injury. Case Report and Review of the Literature (erratum appears in J Neurosurg, 97(3 Suppl): 405-406, 2002). Journal of Neurosurgery, 97(2 Suppl): 252-265, 2002.
52. **McDonald JW**, Sadowsky C. Spinal Cord Injury: Doable Therapeutics. Lancet, 359: 417-425, 2002.
53. **McDonald JW** and Howard MJ. Repairing the damaged spinal cord: a summary of our early success with embryonic stem cell transplantation and remyelination. Prog Brain Res. 137: 299-309. Review, 2002.
54. Becker D, Sadowsky CL, **McDonald JW**. Restoring Function after Spinal Cord Injury. Neurologist, 9(1): 1-15, 2003.
55. Leuchtmann EA, Ratner AE, Vijitruth R, Qu Y, Farhangrazi ZS and **McDonald, JW**. AMPA Receptors are the Major Mediators of Excitotoxic Death in Mature Oligodendrocytes. Neurobiology of Disease, 14(3): 336-348, 2003.
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57. **McDonald JW**, Becker D. Spinal Cord Injury: Promising Interventions and Realistic Goals. American Journal of Physical Medicine & Rehabilitation, 82(10 Suppl): S38-49, 2003.
58. **McDonald JW**, Becker D, Holekamp TF, Howard M, Liu S, Lu A, Lu J, Platik MM, QU Y, Stewart T, Vadivelu S: Repair of the injured spinal cord and the potential of embryonic stem cell transplantation. J. of Neurotrauma 21(4):383-393, 2004.
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McDonald JW and Johnston MV. Physiological and pathophysiological roles of excitatory amino acids during central nervous system development. *Brain Res. Rev.*, 15: 41-70, 1990.

McDonald JW and the Research Consortium of the Christopher Reeve Paralysis Foundation. Repairing the Damaged Spinal Cord. *Scientific American*, September: 64-73, 1999.

McDonald JW, Gottlieb DI and Choi DW. Reply to "What is a functional recovery after spinal cord injury?" *Nature Med.*, 6:358, 2000.

McDonald JW. ES cells and Neurogenesis. In *Stem Cells and CNS Development*. M. Rao (Ed), The Human Press Inc., Totowa, NJ, pp. 207-261, 2001.

McDonald JW, Grill WM, Heetderks W, Kocsis J, Weinrich M, Peckham PH. At The Interface: Convergence of Neural Regeneration and Neural Prostheses for Restoration of Function. *Journal of Rehabilitation Research & Development*, 38:633-639, 2001.

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McDonald JW, Sadowsky C. Spinal Cord Injury: Doable Therapeutics. *Lancet*, 359:417-425.

Kerr D and The Transverse Myelitis Consortium Working Group. Proposed Diagnostic Criteria and Nosology of Acute Transverse Myelitis. *Neurology*, in press.

McDonald JW and Howard MJ. Repairing the Damaged Spinal Cord: A Summary of Our Early Success with Embryonic Stem Cell Transplantation and Remyelination. *Progress in Brain Research*. 137: 299-309, 2002

Sadowsky C, Volshteyn O, Schultz L, **McDonald JW**. Rehabilitation in Practice: Spinal cord injury. *Disability and Rehabilitation*, 24(13): 680-687, 2002.

Chapters in Books and Other Non-refereed Materials:

1. **McDonald JW**, Silverstein FS, Cardona D, Uckele J, Chen R and Johnston MV. Neuroprotective effects of MK-801 and other compounds on perinatal hypoxic-ischemic injury. In Sigma Opioid-PCP like Compounds As Molecular Probes in Biology. E.F. Domino and K.M. Kamenka (Eds.), NPP Press, pp. 697-708, 1988.
2. Johnston MV, **McDonald JW** and Silverstein FS. Role of synaptic mechanisms in hypoxic-ischemic brain injury and birth defects. In J.W. Swann (Ed.), Disorders of the Developing Nervous System: Changing Views on Their Origins, Diagnoses and Treatments, Alan & Liss, New York, pp. 69-92, 1988.
3. **McDonald JW**, Silverstein FS and Johnston MV. Comparison of neuroprotective effects of competitive and non-competitive NMDA antagonists against NMDA mediated neurotoxicity in an in vivo perinatal rat model. In Recent Advances in Excitatory Amino Acid Research. E.A. Cavalheiro, J. Lehmann, L. Turski (Eds.), Neurology and Neurobiology, Vol. 46, Alan R. Liss, New York, pp. 601-604, 1988.
4. **McDonald JW**, Trescher WH and Johnston MV. The pattern and degree of selective vulnerability to excitotoxic brain injury is dependent upon developmental age. In Excitatory Amino Acids, Vol 5. B.S. Meldrum, F. Moroni, R.P. Simon and J.H. Woods (Eds.), Raven Press, New York, pp. 609-614, 1991.
5. Johnston MV, **McDonald JW**, Chen C-K and Trescher WH. Role of Excitatory amino acid receptors in perinatal hypoxic-ischemic brain injury. In Excitatory Amino Acids, Vol 5. B.S. Meldrum, F. Moroni, R.P. Simon and J.H. Woods (Eds.), Raven Press, New York, pp. 711-716, 1991.
6. **McDonald JW** and Johnston MV. Excitatory amino acid neurotoxicity in the developing brain. In NIDA Research Monograph Series- Sigma, PCP, and NMDA receptors, Vol. 133. E.B. DeSouza, D. Clouet, E.D. London (Eds.), National Institute on Drug Abuse, Maryland, pp. 185-205, 1993.
7. Johnston MV and **McDonald JW**. Metabolic and pharmacologic consequences of seizures. In Pediatric Epilepsy, Diagnosis and Therapy. WE Dodson and JM Pellock (Eds), Demos Publication, New York, pp 27-35, 1993.
8. **McDonald JW** and Choi DW. Why Oligodendrocytes Die in Spinal Cord Injury. Brain Works, Dana Publications, 7 (2), 1997.
9. **McDonald JW** and the Research Consortium of the Christopher Reeve Paralysis Foundation. Repairing the Damaged Spinal Cord. Scientific American, September, pp 64-73, 1999.

10. **McDonald JW.** Spinal Cord Injury and Repair. In Diseases of the Nervous System: Clinical Neurosciences and Therapeutic Principles, 3rd Ed., in press.

Abstracts and Presentations:

1. **McDonald JW**, Parnisari RM, Camel JE and Greenough WT. Environmental conditions modulate degeneration and new dendrite growth in cerebellum of senescent rats. Clinical Research, February, 1986.
2. **McDonald JW**, Parnisari RM and Greenough WT. Environmental conditions modulate degeneration and new dendrite growth in cerebellum of senescent rats. The Midwest Student Medical Research Form XVII, February, 1986.
3. Johnston MV, Silverstein FS, Barks J, **McDonald JW**, Young AB, Penney J and Greenamyre JT. Reorganizing glutamate pathways in the developing brain may provide a substrate for hypoxic-ischemic neuronal injury. Sigma opioid-PCP like compounds as molecular probes in biology. July, 1987.
4. **McDonald JW**, Silverstein FS, and Johnston, MV. The glutamate antagonist MK-801 attenuates perinatal hypoxic-ischemic brain injury. Child Neurology Society, October, 1987. Ann. Neurol. 22:407, 1987.
5. **McDonald JW**, Silverstein FS, Cardona D and Johnston MV. The glutamate antagonist MK-801 blocks hypoxic-ischemic brain necrosis in immature rats. Society for Neurosci. Abst. 13:300.14, 1987.
6. **McDonald JW**, Silverstein FS and Johnston MV. 3H-TCP binding hypoxic-ischemic brain, The Society for Pediatric Research, 1988.
7. **McDonald JW**, Silverstein FS and Johnston MV. The glutamate antagonist MK-801 blocks N-methyl-D-aspartate mediated neurotoxicity in immature brain. American Academy of Neurology, April, 1988.
8. **McDonald JW**, Silverstein FS and Johnston MV. Systemic administration of MK-801 protects against N-methyl-D-aspartate (NMDA) and quisqualate (QA) mediated neurotoxicity in perinatal rats. Mich. chapter Neurosci Meeting, March, 1988.
9. **McDonald JW**, Silverstein FS and Johnston MV. NMDA neurotoxicity in 7 d.o. rats offers an in vivo model to rapidly screen neuroprotective drugs: Neuroprotective effects of MK-801 and related compounds. Neurochemistry International, 12(1):37, 1988.
10. **McDonald JW**, Silverstein FS and Johnston MV. Developmental alteration in NMDA receptor/channel binding characteristics and its relationship to neurotoxicity in immature brain. Child Neurology Society, Halifax, Nova Scotia, September 1988.

11. **McDonald JW**, Penney JB, Johnston MV and Young AB. Quantitative autoradiography of [3H]-glycine binding to the glycine receptor associated with the NMDA receptor operated channel. Society for Neurosci. Abst. 14:199.10, 1988.
12. Johnston MV, Silverstein FS and **McDonald JW**. MK-801 pretreatment enhances NMDA mediated brain injury and alters NMDA receptor and PCP receptor binding characteristics in perinatal rats. Society for Neurosci. Abst. 14:299.11, 1988.
13. Silverstein FS, **McDonald JW** and Johnston MV. 3H-TCP binding in hypoxic-ischemic brain. Society for Neuroscience Abst. 14:169.3, 1988.
14. **McDonald JW**. Neuroprotective effects of NMDA receptor antagonists in two models of brain injury. Cambridge Neuroscience, April 1988, lecture.
15. **McDonald JW**, Silverstein FS and Johnston MV. NMDA receptor binding is increased acutely in rats treated with the non-competitive NMDA receptor antagonist MK-801. University of Michigan Student Medical Research Forum, Ann Arbor, MI, October, 1988.
16. **McDonald JW**, Young AB and Johnston MV. The role of the NMDA receptor/channel complex in neuronal injury. Program and Proceedings of MSTP Scientific Retreat, 42-46, 1988.
17. **McDonald JW**, Garofalo EA, Hood T, Sackellares C and Johnston MV. Distribution of excitatory amino acid and GABA receptor binding in hippocampus of patients with epilepsy. American Academy of Neurology Abst. 1989, in press.
18. Uckele J, **McDonald JW**, Johnston MV and Silverstein FS. Glycine antagonists attenuate NMDA mediated brain injury. Soc. Ped. Res. Absts. 1989, in press.
19. **McDonald JW**. Roles of excitatory amino acid neurotransmitters in the physiology and pathophysiology of brain development. Johns Hopkins School of Medicine, lecture.
20. Uckele JE, **McDonald JW**, O'Mara K, Silverstein FS and Johnston MV. Chronic MK-801 treatment enhances NMDA recognition site binding in perinatal rats. Soc. Neurosci. Abst. 15:86.2, 1989.
21. **McDonald JW**, Johnston MV and Young AB. Ontogeny of the receptors comprising the NMDA receptor complex. Soc. Neurosci. Abst. 15:86.3, 1989.
22. Johnston MV, **McDonald JW**, Hood T, Sakellares C, Garofalo E, McKeever PE, Troncoso J and Gilman S. Elevated NMDA receptor and reduced GABA receptor

- binding in hippocampus from patients with temporal lobe epilepsy. Soc. Neurosci. Abst. 15:478.14, 1989.
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PATENTS

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**OLIGODENDROCTYE CELL CULTURES AND METHODS FOR THEIR
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